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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,208	10/06/2000	Harold A. Robertson	36541-0005	8654

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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1636	4

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/680,208	ROBERTSON ET AL.	
	Examiner	Art Unit	
	Quang Nguyen	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to a composition for treating a CAG repeat disorder comprising a compound which modulates PDE10A expression and a pharmaceutically acceptable carrier, and method of treating a subject having a CAG repeat disorder using the same, classified in class 514, subclass 250, for example.

II. Claims 8-12, drawn to a method for identifying a compound which inhibits or promotes a CAG repeat disorder using an animal having PDE10A, classified in class 800, subclasses 3, 8, for examples.

III. Claims 13-14, drawn to a method for identifying a compound which inhibits or promotes a CAG repeat disorder using a host cell containing PDE10A, classified in class 435, subclasses 6, 325, for examples.

IV. Claims 15-19, drawn to a method for detecting the presence of or the predisposition for a CAG repeat disorder by determining the level of expression of PDE10A RNA in an individual relative to a predetermined control level of expression, classified in class 435, subclass 6.

Additionally, should Applicants elect Group I, II, III or IV, **further group restriction** is required because claims 1-2 and 4-6; 8-11; 13; 15-18, respectively comprise a plurality of disclosed patentably distinct CAG repeat disorders (a) Huntington's disease, (b) Parkinson's disease, (c) Schizophrenia, (d) Alzheimer's

disease, (e) stroke, and (f) trauma that lack unity of invention. Applicants is required under 35 U.S.C. 121 to elect a specific CAG repeat disorder.

Furthermore, should Applicants elect Group I, **further group restriction** is required because claims 1-3 and 5-7 comprise a plurality of disclosed patentably distinct compounds having no common core structure that lack unity of invention for treating a CAG repeat disorder. The plurality of disclosed patentably distinct compounds comprise:

> (a) quinpirole, (b) alloxan, (c) miconazole nitrate, (d) MDL-12330A, (e) tetracyline derivatives, (f) KS-505, (h) IC224, (i) SCH 51866, (j) IBMX, (k) dipyridamole, and (l) a compound recited in claim 4.

Applicant is required under 35 U.S.C. 121 to elect a specific compound.

The inventions are distinct, each from the other because of the following reasons:

Inventions I to IV are drawn to distinct and mutually exclusive methods. Invention I is directed to a method for treating a subject having a CAG repeat disorder; Invention II is drawn to a method for identifying a compound which inhibits or promotes a CAG repeat disorder using an animal having PDE10A; Invention III is directed to a method for idendifying a compound which inhibits or promotes a CAG repeat disorder using a host cell containing PDE10A; and Invention IV is drawn to a method for detecting the presence of or the predisposition for a CAG repeat disorder by determining the level of expression of PDE10A RNA in an individual relative to predetermined control level of expression. The methods require different starting materials (patients suffering from a CAG repeat disorder, animals or host cells containing PDE10A or individuals predisposed or at risk for a CAG repeat disorder),

different steps (e.g., a compound is not administered to an individual in the method of invention IV), different end-results and they require different technical considerations for achieving different desired end results (e.g., therapeutic results are not required for methods of inventions II-IV; compounds promoting a CAG repeat disorder are required for methods of inventions II and III).

Additional group restriction is also required because there is a lack of unity of invention among the various CAG repeat disorders disclosed in the present application. There is no common etiology, disease progression, symptoms among Huntington's disease, Parkinson's disease, stroke, Alzheimer's disease and others. As such, methods for treating these different CAG repeat disorders require different materials(e.g., patients suffering from these diseases) and considerations for achieving the desired therapeutic end results. Similarly, different materials and considerations are required for identifying compounds promoting or inhibiting or diagnosing these various CAG repeat disorders.

With respect to further group restriction requirement for a specific compound in the invention of Group I, claims 1-3 and 5-7 comprise a plurality of disclosed patentably distinct compounds having no substantial common core structure that lack unity of invention. Additionally, these patentably distinct compounds have different biochemical properties and therefore different considerations are needed to evaluate the effectiveness of each compound for treating a CAG repeat disorder as encompassed by the claims.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.

Quang Nguyen, Ph.D.

DAVE T. NGUYEN
PRIMARY EXAMINER